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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/828,479

04/21/2004

Michael R. Johnson

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4867

22850

7590

12/05/2006

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EXAMINER

TUCKER, ZACHARY C

ART UNIT

PAPER NUMBER

1624

DATE MAILED: 12/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/828,479

Applicant(s)

JOHNSON, MICHAEL R.

Examiner

Zachary C. Tucker

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 125-246 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 125-246 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 21Apr04, 12Jul06

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____.

Art Unit: 1624

Requirement for Restriction

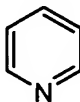
Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 125-162, 164, 167, 171, 173, 176, 177, 184, 188-193, 196-202, 204, 205, 207-210, 212-246 (all in part) and claims 163, 165, 166, 168-170, 172, 174, 175, 178-183, 185-187, 194, 195, 203, 206 and 211, drawn to a method of effecting in a subject at least one member selected from a group consisting of twenty-six different therapeutic outcomes, [comprising] administering to a subject an effective amount of a compound represented by formula (I), wherein the "Q" variable-containing ring in formula (A) of formula (I) is a phenyl ring –



classified in class/subclass 514/255.06.

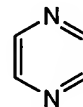
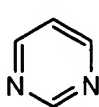
- II. Claims 125-162, 164, 167, 171, 173, 176, 177, 184, 188-193, 196-202, 204, 205, 207-210, 212-246 (all in part), drawn to a method of effecting in a subject at least one member selected from a group consisting of twenty-six different therapeutic outcomes, [comprising] administering to a subject an effective amount of a compound represented by formula (I), wherein the "Q" variable-containing ring in formula (A) of formula (I) is a pyridine ring –



classified in class/subclass 514/255.05.

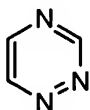
Art Unit: 1624

- III. Claims 125-161, 164, 167, 171, 173, 176, 177, 184, 188-193, 196-202, 204, 205, 207-209, 212-246 (all in part), drawn to a method of effecting in a subject at least one member selected from a group consisting of twenty-six different therapeutic outcomes, [comprising] administering to a subject an effective amount of a compound represented by formula (I), wherein the "Q" variable-containing ring in formula (A) of formula (I) is a 1,3-diazine, 1,2-diazine or 1,4-diazine ring -



classified in class/subclasses 514/252.02 (when the "Q" ring is a 1,2-diazine), or 514/252.11 (when the "Q" ring is 1,4-diazine).

- IV. Claims 125-161, 164, 167, 171, 173, 176, 177, 184, 188-193, 196-202, 204, 205, 207, 212-246 (all in part), drawn to a method of effecting in a subject at least one member selected from a group consisting of twenty-six different therapeutic outcomes, [comprising] administering to a subject an effective amount of a compound represented by formula (I), wherein the "Q" variable-containing ring in formula (A) of formula (I) is a 1,2,4-triazine or 1,3,5-triazine ring -



classified in class/subclass 514/242 (when the "Q" ring is 1,2,4-triazine) or 514/241 (when the "Q" ring is 1,3,5-triazine).

The inventions are independent or distinct, each from the other because:

Art Unit: 1624

Inventions I, II, III and IV are directed to related inventions. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed do not overlap in scope and have materially different design (the molecular structure of the therapeutic agent is different). Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants. The methods wherein the compounds of formula (I) which comprise the respective different heterocycles as the "Q" containing ring are administered are patentably distinct over one another, and the method wherein the compound of formula (I) comprises a phenyl ring as the "Q" containing ring is also patentably distinct from all of the others.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction were not required because the inventions have acquired a separate status in the art due to their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include election of an invention to be examined even though the requirement be traversed (37 CFR 1.143).

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly

Art Unit: 1624

and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Comments

These comments are offered as a courtesy to applicant, in the interest of compact prosecution. Applicant may wish to respond to the comments by amending the claims appropriately.

In the base claim, claim 125, there is no recitation of a method descriptor. That is, the word "comprising" or the phrase "consisting of" is not recited before the method step "administering." Consequently, the claim 125 amounts to a recitation of "A method of effecting in a subject at least one member selected from the group consisting of promoting ocular hydration... administering to a subject an effective amount of a compound represented by formula (I):" The verb "administering" is a member of the Markush group from which the result that is effected by the practice of the method is selected.

Applicant should amend claim 125 so that the word "comprising" appears after the phrase "otitis media" and before the word "administering."

The instant application is one of a large group of related cases, the vast majority

Art Unit: 1624

of which the undersigned examiner has prosecuted or will be prosecuting in the near future. In conversations with applicant's counsel, Mr. James J. Kelly, permission has been given to the examiner to cancel the claim drawn to "a method of restoring mucosal defense" in all of those other cases thus far. In the instant application, the same is recommended, as the term "restoring mucosal defense" is not clear and well-defined as to exactly what it covers. Additionally, the methods drawn to "preventing ventilator-induced pneumonia" has been amended in all of those related cases so that "*treating* ventilator-induced pneumonia" is instead claimed. The same is recommended in the instant application, as prevention of the condition is not deemed enabled by the disclosure. It may also be possible to adopt other claim language that is acceptable to both parties for amendment of the method drawn to "prevention of ventilator-induced pneumonia," such as "slowing the progression of ventilator-induced pneumonia" or "inhibiting the development of ventilator-induced pneumonia."

Conclusion

Any inquiry concerning this communication should be directed to Zachary Tucker whose telephone number is (571) 272-0677. The examiner can normally be reached Monday to Friday from 5:45am to 2:15pm. If Attempts to reach the examiner are unsuccessful, contact the examiner's supervisor, James O. Wilson, at (571) 272-0661.

The fax number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.



Zachary C. Tucker
Primary Examiner
Art Unit 1624